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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

HFI-35

New York District

Food & Drug Administration  
850 Third Avenue  
Brooklyn, NY 11232

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

DEC 16 1998

Mr. Uziel Frydman  
President  
Sherwood Brands, Inc.  
6110 Executive Boulevard, Suite 1080  
Rockville, MD 20852

**Ref: NYK-1999-13**

Dear Mr. Frydman:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On October 22, 1998 FDA sent an electronic message to your customs broker [The A. W. Fenton Company, Inc., Jamaica, NY] that chocolate filled toffees, an item from entry 885-0730449-6 must be held intact and not distributed. This product was to be examined or sampled by FDA when available. Sherwood Brands or your import broker were requested to provide FDA with a location and a time for our examination or sample collection of the following:

Entry 885-0730449-6, line 2-1, Cows brand, Chocolate Filled Toffees, a total of 9,170 cases, each containing 12 x 7 oz. packages.

Product location was provided on October 27. Subsequently, on November 12, 1998 FDA collected a sample of the product at Ultimate Distribution Warehouse, Edison, NJ. At that time, we determined only 230 cartons remained, while 6,940 of the 7,130 cartons had been sold and distributed.

This action taken by your firm is in violation of 21 CFR 1.90 which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from FDA. A "Release" by the U. S. Customs Service is a conditional release which merely permits you to take possession of the shipment. When other Federal agencies, such as FDA also exercise jurisdiction over a product offered for importation, its release must also be obtained before any of the product may be legally distributed.

**Mr. Uziel Frydman, President**  
**Sherwood Brands, Inc.**

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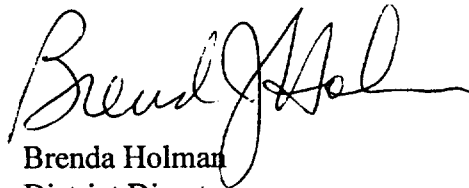
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice, such as seizure, injunction, or automatic detention to ensure that imported products are held intact until released by FDA. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the reoccurrence of the violation.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will also be on public display with any confidential, personal or commercial information purged.

Your response should be addressed to the Food and Drug Administration, Attention: Joseph V. Sollazzo - Compliance Officer, Port Elizabeth Resident Post, 1201 Corbin Street, Elizabeth, New Jersey 07201 (telephone 732-645-2386 extension 20).

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda Holman", with a stylized flourish at the end.

Brenda Holman  
District Director  
New York District Office

cc: The A. W. Fenton Company, Inc.  
JFK International Airport  
Building #75, Suite 203A  
Jamaica, NY 11430-4015